REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons which follow.

Claims 6, 10-17, and 22-24 are requested to be cancelled. As such, claims 1-5, 7-9, 18-21, and 25-29 currently are pending. Claims 8 and 9 remain withdrawn from consideration. As such, claims 1-5, 7, 18-21, and 25-29 currently are under consideration in this application.

Applicants have amended the specification to include SEQ ID NO: identifiers for the nucleotide sequences of NCA-90 and NCA-95. These sequences are presented in Oikawa *et al.*, *Biochem. Biophys. Res. Commun.*, 146:464-460 (1987) and Berling *et al.*, *Cancer Res.*, 50:6534-6539 (1990), respectively, both of which references were incorporated by reference in the specification as filed. In addition, Applicants have submitted corresponding Sequence Listings for NCA-90 and NCA-95. The amended specification contains no new matter, and Applicants have enclosed herewith a declaration that states that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569 (C.C.P.A. 1973).

In the Office Action dated August 12, 2003, the Examiner rejected claims 1-5, 7, 18-21, and 25-29 under 35 U.S.C. § 112, first paragraph, as "failing to comply with the enablement requirement." In particular, the Examiner contends that because the claims recite methods that utilize specific antibodies, the specification must recite a listing of the sequence of the antigens to which the antibodies specifically bind. The Examiner contends that the sequences of the antigens is "essential material" and as such, the sequences must not be incorporated by reference. Rather, the specification must be amended to specifically recite

the sequences of the antigens to which the antibodies recited in the claims bind. In the Office Action, the Examiner stated that "[w]ithout the sequences of NCA-90, NCA-95, CD-33, and CD-15[,] one of skill in the art would not be able to make and or use the claimed method without undue experimentation." (See Office Action, mailed August 12, 2003, page 4.) Applicants respectfully disagree with the Examiner as indicated below. However to facilitate prosecution of this application, Applicants have amended the specification, where possible, to specifically refer to the sequence of the antigens by reciting a SEQ ID NO. identifier and by including a Sequence Listing. In particular, Applicants have amended the specification to include SEQ ID NO. identifiers for the nucleic acid sequences and amino acid sequences corresponding to NCA-90 and NCA-95 and to include Sequence Listings for NCA-90 and NCA-95.

Applicants respectfully disagree with the Examiner's argument that the sequences of the particular antigens are "essential material" because "without the sequences...one of skill in the art would not be able to make and or use the claimed method without undue experimentation." First, anti-NCA-90, anti-NCA-95, anti-CD33, and anti-CD-15 antibodies are commercially available. As stated in MPEP § 2164.01(b), "[a] key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnology area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening...the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available." MPEP § 2164.01(b) (8th Edition, 2001)(citing *In re Ghiron*, 442 F.2d 985, 991 (C.C.P.A. 1971)(emphasis added).

Second, it has been determined that "availability of [a] biological product via a public depository provide[s] an acceptable means of meeting the written description requirement and the enablement requirements of 35 U.S.C. 112, first paragraph." MPEP § 2164.06(a) (citing *In re Argoudelis*, 434 F.2d 1390 (C.C.P.A. 1970)(emphasis added)). By analogy, the nucleotide sequences of NCA-90, NCA-95, and CD-33 have been deposited in the GenBank® database that is made available by the National Library of Medicine on the National Center for Biotechnology Information's website ("NCBI"). See http://www.ncbi.nlm.nih.gov. For example, the specific nucleotide and amino acid sequences for NCA-90 are made available at: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=nucleotide&list_uids=180230&dopt=GenBank&term=oikawa+kosaki, as submitted by Oikawa *et al.* The specific nucleotide and amino acid sequences for NCA-95 are made available at: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=nucleotide&list_uids=29918&dopt=GenBank, as submitted by Berling *et al.* The specific nucleotide and amino acid sequence for CD-33 are made available at: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=nucleotide&list_uids=4502654&dopt=GenBank, which cites several submitting authors. As such, it would not entail undue experimentation for one skilled in the art to obtain the sequences of NCA-90, NCA-95, and CD-33. One skilled in the art need only visit the NCBI website and access the GenBank® database.

In regard to CD-33, the instant specification describes anti-CD-33 antibodies by referring to U.S. 6,007,814. Applicants first note that under USPTO practice, an application may incorporate "essential material" by reference to a U.S. patent or application. (See MPEP

§ 608.01(p) I.A.). The '814 patent does not explicitly disclose the sequence of anti-CD-33, and as such, Applicants cannot amend the specification to recite the sequence of CD-33 by relying on the disclosure in the '814 patent. However, Applicants respectfully note that even though the specification of the '814 patent does not explicitly recite the sequence of CD-33, the '814 patent includes claims to anti-CD-33 antibodies (*i.e.*, M195). In contrast, Applicants' claims recite methods of using anti-CD-33 antibodies, which are now commercially available.

In regard to CD-15, Applicants note that CD-15 is not a protein. Rather, CD-15 is a triasaccharide called 3-fucosyl-N-acetyllactosamine, also known as X-hapten. As such, CD-15 does not require a sequence listing. One skilled in the art would know that anti-CD-15 antibodies can be created by using 3-fucosyl-N-acetyllactosamine as an antigen. Further, anti-CD-15 antibodies are commercially available.

As such Applicants request that the Examiner reconsider the rejection of claims 1-5, 7, 18-21, and 25-29, under 35 U.S.C. § 112, first paragraph.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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